DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95G–0009]

The American Dairy Products Institute; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 1G0371) proposing to affirm that the use of whey protein isolate and dairy product solids is generally recognized as safe (GRAS) as direct human food ingredients. Those food ingredients were redefined from the original submission containing specifications for reduced lactose whey, reduced minerals whey, and whey protein concentrate.

FOR FURTHER INFORMATION CONTACT: Arletta M. Beloian, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3082.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 3, 1995 (60 FR 6713), FDA announced that a petition (GRASP IG0371) had been filed by The American Dairy Products Institute, 130 North Franklin St., Chicago, IL (c/o Keller and Heckman), Washington, DC. This petition proposed that the use of whey protein isolate and dairy product solids as direct ingredients in food be affirmed as GRAS.

The American Dairy Products Institute has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 21, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1165]

Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi: Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'' This guidance describes the types of information that should be submitted in a premarket notification to support a decision of substantial equivalence for an extracorporeal shock wave lithotripter indicated for the fragmentation of kidney and ureteral calculi. Elsewhere in this issue of the **Federal Register**, FDA is reclassifying renal and ureteral extracorporeal shock wave lithotripters from class III (premarket approval) to class II (special controls).

DATES: Submit written comments at anytime.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (CDRH) (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

In 1998, FDA initiated proceedings to reclassify the extracorporeal shock wave lithotripter for fragmentation of kidney and ureteral calculi from class III (premarket approval) to class II (special controls). To facilitate this reclassification, FDA prepared the document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'' This document is the special control that has been established to support reclassification to class II, and also provides general guidance to industry on the content of premarket notifications for these devices.

On July 30, 1998, a meeting of the Gastroenterology and Urology Devices Advisory Panel (the Panel) was held to seek its recommendations on this proposed reclassification, including advice on special controls and the content of premarket notifications. The Panel unanimously voted to reclassify the extracorporeal shock wave lithotripter for the fragmentation of kidney and ureteral stones into class II. Comments from the Panel have been incorporated into this guidance document.

In the **Federal Register** of February 8, 1999 (64 FR 5987 to 5996), FDA published its proposal to reclassify the extracorporeal shock wave lithotripter for fragmentation of kidney and ureteral calculi to class II, as well as its announcement of the availability of the draft document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' (64 FR 6100 to 6101). Both the proposed reclassification and the notice of availability provided an opportunity for public comment, which closed May 10, 1999.

Based on the comments received on the draft guidance document, the following substantive changes have been incorporated into the revised version being made available at this time:

1. Section 8.D (Clinical Performance Testing) was revised to more clearly state the recommended sample size. The guidance document now states that the study should enroll a total of 20 patients